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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,636	07/27/2000	Gary Karlin Michelson M D	102.0003-04000	6124
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MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER SEVERSON, RYAN J	
			ART UNIT	PAPER NUMBER
			3731	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 09/626,636	Applicant(s) MICHELSON M D, GARY KARLIN	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-176, 178-256, 258-276, 278-318 and 320-343 is/are pending in the application.
- 4a) Of the above claim(s) 185-189, 196-200, 203-206, 227-236 and 239-246 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 172-176, 178-184, 190-195, 201, 202, 207-226, 237, 238, 247-256, 258-276, 278-318, 320-343 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but do not place the application in condition for allowance.
2. Regarding newly added limitation (claims 172, 219, 248, and 338) "...said guard having a concave curvature oriented toward and approximating..." the guards of the cited references are cylindrical (as are the guards of applicants invention) and therefore have a concave curvature oriented toward and approximating the vertebral bodies. To clarify, the guard of applicant's invention is circular in cross-section, and since the cited references have this identical structure (the circular cross-section), the limitations of the claims have been met.
3. Regarding applicant's argument with respect to claims 207, 289, and 332, Kuslich reference clearly shows side openings (see figure 12, for example), and therefore applicant's argument is not persuasive.
4. Regarding applicant's argument with respect to claims 248 and 332, Examiner agrees with applicant's assertion that Ma does not disclose the flat portion. However, as indicated in the previous office action and repeated below, it is well known in the art to have this flat portion to limit the depth of penetration. An example of such a configuration was cited previously and is cited once again below.

5. Regarding applicant's argument with respect to claims 248 and 332, although the drill guide may be removed prior to insertion of a graft or dowel, the guide is certainly *capable* of being left in place to assist in implantation of a graft or dowel. The limitations "having a passage for providing guided access to a disc space and vertebral bodies adjacent the disc space" and "to permit the movement of a spinal implant therethrough" and merely functional limitations, and thereby a structure *capable* of performing the recited functional limitation meets the claim limitations.

Claim Objections

6. Claim 176 is objected to because of the following informalities: It appears applicant inadvertently omitted the phrase "of claim 172" following "apparatus" in the first line of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 172, 219, 248, and 338 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what surface is concave and oriented toward and approximating the contour of the vertebral bodies.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 172-176, 178-184, 190-195, 201, 202, 207-226, 237, 238, 247-256, 258-276, 278-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (5,015,255) in view of Cozad (5,049,150).** Kuslich discloses a guard (24), a distractor (fig. 5), a cap/an impact end member/footplate (figs. 6, 7); openings (35, fig. 11), spinal implants (103, col. 8, lines 48-60), the size of the guard (col. 9, line 10 to col. 10, lines 32), and an implant driver (inherent feature since the bone chips need to be impacted into the cavity). Kuslich fails to disclose engaging portions and flat portions between the engaging portions as claimed. Cozad disclose guard for bone surgery and including engaging portions and flat portions as claimed (fig. 1) for preventing over-penetration of the engaging portions into bone. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the engaging portion and flat portions in view of Cozad into Kuslich's guard sleeve (104) in order to provide an engage mechanism that prevent the guard from moving so that the insertion could be more accurate.

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11. Regarding the implant driver and implant having structure as claimed, Kuslich (5,015,255) in view of Cozad (5,049,150) further in view of Kuslich et al. (5,489,307). Although, Kuslich '255 does not disclose an implant and an implant driver having structure as claimed, attention is directed to Kuslich et al. '307 reference which discloses an implant and an implant driver as claimed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an implant and an implant driver in view of Kuslich et al. '307 into the apparatus of Kuslich et al. in view of Cozad in order to increase the probability of a successful fusion (see the motivation in Kuslich et al. '307 reference, col. 1, lines 27-39).

12. **Claims 172-176, 178-184, 201, 202, 247-256, 258-269, 276, 278-288, and 331-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al. (3,848,601) further in view of knowledge well known in the art.** Ma et al. disclose all the limitations of the claims except for a presence of a flat portion between spine engaging portions. Although, Ma et al. disclose the depth limit configuration does not including a flat portion between the engaging portions or penetrating portions, it is known in the art to have depth limit configuration including a flat portion between the engaging portions of penetrating portions (see Staubli 5,058,275). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a flat portion between penetration portions of the chisel of Ma et al.'s device for limit the depth penetration of the chisel. Doing so would amount to mere substitution of one configuration for another configuration within the art that would perform equally well in the Ma et al.'s device.

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13. **Claims 172-176, 178-184, 201, 202, 247-256, 258-269, 276, 278-288, and 331-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Codman (Signature Series 4) in view of Cozad (5,049,150).** Codman disclose all the limitations of the claims except for a presence of the engaging portions do not substantially increase the outer cross sectional dimension of the guard near the distal end of the guard. It is well known in the art to have a guide sleeve having penetrating members and a flat portion formed integrally with the sleeve for example, Cozad reference discloses engaging portion do not substantially increase the outer cross sectional dimension of the guard and formed integrally with the sleeve. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Codman reference by having the a guide sleeve having penetrating members and a flat portion formed integrally with the sleeve to reduce the step of making and material for forming a guide sleeve.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.S.

Ryan Severson
July 20, 2007


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER

7/20/07